

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3901. Misbranding of sulfadiazine tablets, Nembutal Sodium capsules, Tuinal capsules, diethylstilbestrol perles, and Dexedrine Sulfate tablets. U. S. v. Henry R. Namour and John C. Wicks. Pleas of nolo contendere. Imposition of sentence suspended and defendants placed on probation for 1 year. (F. D. C. No. 30025. Sample Nos. 76416-K, 76417-K, 77107-K to 77109-K, incl., 77112-K, 77131-K, 77132-K.)

INFORMATION FILED: September 11, 1951, Eastern District of Arkansas, against Henry R. Namour, a partner in the partnership trading as Henry's Drug Store, Helena, Ark., and John C. Wicks, pharmacist for the firm.

INTERSTATE SHIPMENT: From the States of Missouri, Tennessee, Indiana, and Pennsylvania, into the State of Arkansas, of quantities of *sulfadiazine tablets*, *Nembutal Sodium capsules*, *Tuinal capsules*, *diethylstilbestrol perles*, and *Dexedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about March 7, 8, and 9, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

John C. Wicks was charged with the violations involved in the first 5 counts of the information, and Henry R. Namour was charged with the violations involved in the remaining 3 counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing accurate statements of the quantity of the contents and, with the exception of 1 lot of *Tuinal capsules* and the *diethylstilbestrol perles*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *Nembutal Sodium capsules* and the *Tuinal capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* bore no label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 18, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendants on probation for 1 year.

3902. Misbranding of Pabst Okay Special. U. S. v. 33 Bottles * * *. (F. D. C. No. 34094. Sample No. 35968-L.)

LIBEL FILED: November 3, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 26, 1952, by Myers Laboratories, Inc., from Warren, Pa.

PRODUCT: 33 bottles of *Pabst Okay Special* at Cleveland, Ohio. Examination disclosed that the product was a dark green liquid with a bitter and somewhat burning taste and that it consisted essentially of plant extractives, chloroform, alcohol, and volatile oils.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the circular enclosed in the retail carton, represented and suggested that when the article was taken in conjunction with the diet recommended in the circular and with other treatments recommended therein, the article was an adequate and effective treatment for gonorrhea, which representations and suggestions were false and misleading since the article, either alone or when taken in conjunction with the recommended diet and other treatments recommended, was not an adequate and effective treatment for gonorrhea.

Further misbranding, Section 502 (a), the labeling of the article represented and suggested also that the article would reduce the discharge of pus due to gonorrhea and other venereal diseases, which representations and suggestions were false and misleading since the article was not effective in the reduction of the discharge of pus due to gonorrhea or other venereal diseases; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which the article was intended.

DISPOSITION: December 15, 1952. Default decree of condemnation and destruction.

3903. Misbranding of Cystex, Romind, and Mendaco. U. S. v. 48 Dozen Packages, etc. (F. D. C. No. 33257. Sample Nos. 13847-L to 13849-L, incl.)

LABEL FILED: June 3, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about November 10 and December 5 and 28, 1951, and January 17, February 5 and 23, and April 3 and 30, 1952, by the Knox Co., from Newark, N. J.

PRODUCT: 48 dozen \$1.00-size packages and 24 dozen \$2.00-size packages of *Cystex*, 33 dozen \$1.00-size packages and 13 dozen \$2.00-size packages of *Romind*, and 19 dozen \$0.75-size packages, 36 dozen \$1.25-size packages, and 18 dozen \$2.50-size packages of *Mendaco*, at Denver, Colo.

RESULTS OF INVESTIGATION: On March 30 and April 13, 1952, in editions of the local newspaper, there appeared advertisements for *Cystex* placed by an advertising agency for and on behalf of the Knox Co.

LABEL, IN PART: "Cystex * * * Each Tablet contains Acetophenetidin 1½ grains, Methenamine and Benzoic Acid."

NATURE OF CHARGE: *Cystex*. Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not capable of fulfilling the promises of benefit made for it: (Carton) "Usually gives splendid palliative relief in acid urine for minor discomfort and irritation due to temporary non-organic and non-systemic Kidney and Bladder disturbances," (carton and leaflet entitled "Directions for Use" enclosed in carton) "Directions for use * * * In responsive cases discontinue when not needed for relief * * * Take Cystex long enough for a fair trial, and keep it on hand for quick use if needed again," (leaflet entitled "Directions for Use" enclosed in carton) "Take New Improved Cystex with utmost confidence. It is tried and true," and (leaflet entitled "A letter to you from our president" enclosed in carton) "Knox products * * * usually give very satisfactory results * * * try Knox Products, which your family may require, with the realization that they have proven highly satis-